UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. AEGERION PHARMACEUTICALS, INC., Defendant.	Criminal No. 1:17-cr-10288-WGY **ORAL ARGUMENT REQUESTED** LEAVE TO FILE UNDER SEAL GRANTED ON _____

AEGERION PHARMACEUTICALS, INC.'S MEMORANDUM
IN SUPPORT OF THE PARTIES' AMENDED PLEA AGREEMENT

Defendant Aegerion Pharmaceuticals, Inc ("Aegerion" or the "Company") respectfully submits this memorandum in support of the proposed Amended Plea Agreement, dated October 30, 2017 and entered into pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) (the "Amended Plea Agreement") (Dkt. #16).

The Amended Plea Agreement now before the Court for approval is an important component of a comprehensive global resolution of a joint investigation conducted by the Department of Justice ("DOJ") and the U.S. Securities and Exchange Commission ("SEC") (the "Government Investigations"). The global resolution involves five separate settlement agreements with various agencies of the federal government and separate agreements with 28 state attorneys general. This comprehensive settlement acknowledges Aegerion's misconduct, provides for several years of ongoing governmental oversight of Aegerion's operations by several arms of the federal government, and imposes substantial monetary penalties on the Company. The global resolution, at the same time, was necessitated by Aegerion's acute financial condition and reflects a thorough examination of Aegerion's ability to pay, while also recognizing both Aegerion's unprecedented cooperation with the government and the complete

transformation of the Company's leadership and its approach to sales and marketing. Taken together, the sentence set forth in the Amended Plea Agreement punishes Aegerion's past misconduct and establishes a framework to prevent any future misconduct, without significantly exacerbating the serious financial challenges facing Aegerion and potentially harming patients who depend on Aegerion's products to treat their ultra-rare medical conditions.

This settlement comes at an incredibly important juncture for Aegerion. In late 2015, approximately two years into DOJ's investigation, Aegerion's financial condition began to deteriorate rapidly due to both significant changes that that Company initiated in its promotional practices and the introduction of competitor products that treated some, but not all, of the patients who responded favorably to Juxtapid, Aegerion's core product. As a result, sales of Juxtapid in the U.S. began to drop sharply, and they continue to decline to this day.

With its financial situation worsening, Aegerion approached DOJ and SEC to acknowledge its misconduct and commence settlement negotiations that would take into account Aegerion's serious financial situation, as well as significant management changes at Aegerion and its unparalleled cooperation with the government. Over the course of lengthy and extensive negotiations, the government scrutinized Aegerion's financial health, projections, growth plans, and ability to pay substantial fines and penalties. Critically for this Court's consideration of the proper sentence for this conduct, the *entire* senior leadership of Aegerion from the time period of the misconduct has been replaced—Aegerion has a new CEO, new CFO, new COO, new General Counsel, new Head of Research and Development, new Chief Compliance Officer, and new Head of Human Resources. The Aegerion that stands before the Court today is a fundamentally different company, managed and operated by new leadership and employees, compared to the company that engaged in misconduct.

Given the situation facing Aegerion in early 2016, the parties arrived at an agreement that imposed significant penalties—$40 million in combined criminal and civil penalties, including criminal penalties of $7.2 million, a Corporate Integrity Agreement, a Consent Decree with the Food and Drug Administration ("FDA"), a Deferred Prosecution Agreement with the DOJ, and other substantial compliance, monitoring, and reporting responsibilities. Through these agreements (which impose hundreds of pages of obligations on Aegerion), the DOJ, the Office of the Inspector General for the Department of Health and Human Services ("OIG-HHS"), and the FDA will all play a role in overseeing Aegerion. By placing Aegerion on Probation, the Court will also play an important role in ensuring that Aegerion meets all of its compliance obligations.

This settlement provides the Company with a viable path forward, albeit at a heavy price. Since negotiations with the government began in late 2015 and the $40 million agreement in principle was reached in May 2016, Aegerion's financial outlook has weakened even further. Sales of Juxtapid are a fraction of what they once were, and, as a result, Aegerion's net cash reserves are very low. If not for the heavily negotiated payment schedule set forth in the Amended Plea Agreement (and the other settlement agreements), as well as loans from its parent company, Novelion Therapeutics Inc., Aegerion's financial condition would continue to decline, posing a real threat to Aegerion's viability.

The Amended Plea Agreement fully satisfies the objectives of criminal sentencing set forth in 18 U.S.C. § 3553(a). Accordingly, Aegerion respectfully requests that the Court accept Aegerion's plea and impose the sentence set forth in the Amended Plea Agreement.

FACTUAL BACKGROUND

A. Aegerion, Juxtapid, And The Government Investigations

From its founding in 2005 through December 2012, Aegerion focused on developing and commercializing its first product, Juxtapid, which it began marketing in January 2013. Juxtapid

lowers dangerously high levels of cholesterol in patients with homozygous familial hypercholesterolemia ("HoFH"). HoFH is a very rare and life-threatening genetic disorder that impairs the body's ability to remove low-density lipoprotein cholesterol ("LDL-C" or "bad cholesterol") from the blood, resulting in markedly elevated cholesterol levels in the bloodstream and an increased risk of cardiovascular events, such as heart attack and stroke.

In November 2013, during Juxtapid's first year on the market, Aegerion received a subpoena from the DOJ seeking documents relating to Juxtapid. In 2014, the SEC also began investigating Aegerion. The DOJ and SEC investigations proceeded in parallel and focused on a variety of issues generally related to the sales and marketing of Juxtapid, compliance with the FDA-mandated Risk Evaluation and Mitigation Strategy ("REMS") program for Juxtapid, statements to the securities market about the prevalence of HoFH and other performance metrics, and the Company's compliance with the Health Insurance Portability and Accountability Act ("HIPAA").

B. Aegerion's Financial Condition Deteriorates

By mid-2015, Aegerion fundamentally altered its marketing and promotional practices. Juxtapid sales began to plunge due to significant changes in the marketing and promotion of Juxtapid, as well as the introduction of two new products designed to treat HoFH, called PCSK9 inhibitors, that compete with Juxtapid. At the end of 2015, sales of Juxtapid had dropped by 33%, decreasing from nearly $60 million in the third quarter to approximately $40 million in the fourth quarter of 2015. Juxtapid sales have decreased much further since. By the first quarter of 2017, quarterly sales of Juxtapid had dropped to approximately $16 million. As Juxtapid's sales have suffered, so has Aegerion's cash position.

Aegerion's finances are also significantly impacted by its large debt. In August 2014, Aegerion issued $325 million in convertible notes, which it ultimately used to fund the

acquisition of a second product, Myalept, which treats patients with generalized lipodystrophy, another ultra-rare disease. Aegerion completed its acquisition of Myalept in January 2015.

Because Aegerion generates revenue exclusively through sales of Juxtapid and Myalept, the deteriorating performance of Juxtapid poses a real threat to Aegerion's viability. Between July 1, 2015, and July 1, 2016, Aegerion lost 91.3% of its market capitalization, amounting to nearly $491.4 million. By early 2016, with sales dropping precipitously, Aegerion required a capital infusion. Given its significant debt and financial state, Aegerion needed to enter into a strategic transaction. Yet, potential transaction partners were quite wary of the risks posed by the ongoing Government Investigations and refused to invest in the Company until Aegerion could provide clarity as to how those investigations would resolve.

C. The Preliminary Settlement Agreement in Principle

Given all of these factors, in late 2015, Aegerion initiated settlement discussions with DOJ, SEC, OIG-HHS, and FDA. The purpose of the discussions was to determine whether a mutually agreeable resolution could be reached requiring Aegerion to acknowledge its misconduct, establishing oversight over Aegerion's activities, and imposing monetary penalties that would serve as an effective deterrent without extracting a fine that would cripple Aegerion and potentially deprive patients of critical medications.

The settlement negotiations reflected Aegerion's very challenging financial condition. Over many months of negotiations, Aegerion allowed the government virtually unfettered access to information about the Company's financial situation. Aegerion provided the government with detailed financial data and projections, and, on multiple occasions, senior Aegerion executives met with government officials to discuss Aegerion's financial condition, strategic plans, and expected future performance. DOJ's financial experts and auditors scrutinized Aegerion's financial records and thoroughly assessed the amount of money that Aegerion could afford to

pay and a feasible schedule for such payments.

On May 12, 2016, Aegerion reported in its securities filings that it had reached a preliminary agreement in principle with the government. Under this agreement, Aegerion would plead guilty to two misdemeanor Food, Drug, and Cosmetic Act violations, and enter into a Deferred Prosecution Agreement on felony HIPAA charges. The fines and penalties, along with the timing of payments, were heavily negotiated. The government successfully negotiated for protection in the event that Aegerion were to complete a change-of-control transaction or sell its assets. These provisions ensure that Aegerion will comply with its financial obligations to the government in the event that it enters subsequent transactions.

D. Novelion Therapeutics Inc. Acquires Aegerion

Having obtained clarity regarding the impact of the Government Investigations, Aegerion was able to negotiate an agreement with a strategic partner. On June 14, 2016, Aegerion entered into an Agreement and Plan of Merger with Canadian biopharmaceutical company QLT, Inc. When the transaction closed on November 29, 2016, Aegerion became an indirect, wholly owned subsidiary of QLT, which changed its name to Novelion Therapeutics Inc. ("Novelion"). Like Aegerion, Novelion is dedicated to developing treatments for rare diseases. Aegerion remains a subsidiary of Novelion.

Since the merger transaction, Aegerion has borrowed money from Novelion to fund its working capital, with strict borrowing limits and other requirements, including interest. This debt is collateralized by certain Aegerion assets. However, Aegerion's obligations and liabilities remain with Aegerion and not Novelion. Aegerion is not an "alter ego" of Novelion, and the companies remain separate entities. Novelion and Aegerion's assets are not comingled. Aegerion continues to have its own Board of Directors, which meets, makes decisions about Aegerion's business, and maintains its own minutes.

Since the transaction with Novelion, Aegerion's financial position has continued to weaken. For example, in the first quarter of 2017, Juxtapid sales were just $16 million. In light of the sharper than expected decline in sales, management has repeatedly decreased its estimate of 2017 Juxtapid sales. Specifically, in October 2016, Aegerion forecasted that 2017 Juxtapid sales—which had been $158.4 million in 2014 and $213 million in 2015—would be approximately $105 million. By August 2017, as actual results for 2017 continued to come in, management revised projected Juxtapid sales down to $70 to $75 million.

[redacted]

[redacted] The $325 million in convertible notes that Aegerion issued in 2014 to acquire Myalept will come due in 2019.

E. The Settlement Agreements

In September 2017, after a nearly four-year investigation and months of negotiations, Aegerion entered into a definitive series of agreements to accept responsibility for its misconduct and provide a comprehensive monitoring framework that will ensure that Aegerion remains compliant with the law in the future. The settlement provides for admissions of misconduct, years of extensive government oversight of Aegerion, and over $40 million in combined civil and criminal fines and penalties, plus interest. The key terms of the settlement agreements are summarized below.

1. *The Amended Plea Agreement*

In the Amended Plea Agreement, Aegerion agreed to plead guilty to two misdemeanor violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 333(a)(1), 352(f), and 352(y) and pay a $6.2 million fine and $1 million in forfeiture. Am. Plea Agmt. ¶¶ 1, 5(a)-(c)

(Dkt. #16). By entering into the Amended Plea Agreement, Aegerion has agreed to admit responsibility "expressly and unequivocally" for the misconduct detailed in the Information. *Id.* ¶ 1.

Under Section 10 of the Amended Plea Agreement, Aegerion agreed that its President and Novelion's Board of Directors will certify to Aegerion's compliance with the Amended Plea Agreement and the Civil Consent Decree of Permanent Injunction (described below). *Id.* ¶ 10. Aegerion has also agreed to a term of probation of three to five years that incorporates several special conditions of probation. *Id.* ¶ 5(e). One important condition of probation is that Aegerion will not disparage the factual basis for the criminal plea. *Id.* ¶ 5(e)(i).

2. *The Deferred Prosecution Agreement*

Aegerion has also entered into a three-year Deferred Prosecution Agreement ("DPA") charging Aegerion with conspiracy to violate HIPAA. *Id.* Ex. B (Dkt. #16-2) ("DPA"). The DPA provides for robust admissions of wrongdoing in the accompanying Statement of Facts and also includes a non-disparagement clause. DPA at ¶¶ 6-7. This matter is currently pending before Judge Stearns. *United States v. Aegerion Pharm. Inc.*, Criminal No. 17-cr-10289-RGS (D. Mass.) (Dkt. #2).

As part of the Company's ongoing obligations, the DPA requires the Company to "implement and maintain internal controls, policies, and procedures" specifically designed to prevent and detect HIPAA violations, including by maintaining a Compliance and Ethics program. *See* DPA at ¶ 11; *id.* Attach. B ¶¶ 1-3. Under the DPA, Aegerion's President and Novelion's Board of Directors will report to the DOJ on the effectiveness of the Compliance and Ethics Program. *See id.* Attach. B ¶¶ 6-11.

3. *The Civil Settlement Agreement*

The Civil Settlement Agreement (the "CSA") with DOJ and individual *qui tam* Relators

resolves alleged violations of the False Claims Act and similar state statutes. Am. Plea Agmt. Ex. C (Dkt. #16-3) ("CSA"). Pursuant to the CSA, Aegerion will pay a total of $28.8 million to the federal government and 28 separate state Medicaid Fraud Control Units ("MFCUs") which had Medicaid reimbursements for Juxtapid. CSA at ¶ 1. Each of the 28 state MFCUs has also executed separate agreements with Aegerion. The CSA may be voided by either DOJ or Aegerion if this Court declines to impose a sentence within the parameters of the Amended Plea Agreement. CSA at ¶ 1(h). This matter is currently pending before Judge Talwani. *United States ex rel. Clarke v. Aegerion Pharm., Inc.,* Civil No. 13-cv-11785-IT (D. Mass).

4. *The SEC Judgment*

To resolve the SEC's investigation, Aegerion agreed to pay a civil penalty of $4.1 million. *See S.E.C. v. Aegerion Pharm. Inc.*, Civil No. 17-cv-11817-WGY (D. Mass.) (Dkt. #5). In its Complaint, the SEC alleged that Aegerion, through its former CEO, misled investors about a performance metric known as the conversion rate, which describes how many patients actually receive Juxtapid ("converted") after receiving an initial prescription. *Id.* at Compl. ¶ 2 (Dkt. #1). In the SEC settlement, Aegerion agreed to not disparage the SEC Judgment. *Id*. at Consent ¶ 11 (Dkt. #2). This matter is also before this Court, and the Court entered the Final Judgment on September 25, 2017. *See Id.* (Dkt. #5).

5. *The Corporate Integrity Agreement*

Aegerion executed an extensive five-year Corporate Integrity Agreement ("CIA") with OIG-HHS that provides for substantial government oversight and significant penalties for any breaches. Am. Plea Agmt. (Dkt. #16-5) ("CIA"). Under the CIA, Aegerion must maintain a robust Compliance Program that includes a Compliance Officer and a Compliance Committee. *See* CIA §§ III.A.1-3. Aegerion must promulgate comprehensive written policies and procedures regarding the operation of the Compliance Program and appropriate conduct related to sales,

marketing, reimbursement, incentive compensation, and other matters. *See* CIA § III.B. Aegerion will also provide comprehensive training and education regarding the Compliance Program and the requirements of the CIA (*see* CIA § III.C), and establish a disclosure program to allow individuals to report compliance concerns. *See* CIA § III.F.

Aegerion will subject its systems, transactions, risk assessment and mitigation process, and other compliance activities to independent review and analysis by an Independent Review Organization paid for by the Company. *See* CIA §§ III.D-E; CIA App'x. B. The Independent Review Organization is responsible for conducting thorough reviews that are designed to assess Aegerion's systems, policies, and procedures, including an annual review of selected transactions. *See* CIA App'x. B. Additionally, Aegerion agreed that it would monitor interactions between its sales personnel and health care professionals, as well as Aegerion's consultants and its activities related to donations and research grants. *See* CIA §§ III.L-M.

Aegerion will provide an annual certification to OIG-HHS on the effectiveness of its compliance program and submit certifications from various managers overseeing Aegerion's commercial activities. *See* CIA §§ III.A.3-4. Aegerion's reporting obligations under the CIA require that it report (i) any ongoing investigation or legal proceeding alleging that Aegerion engaged in fraudulent or illegal conduct; (ii) any communications with FDA regarding improper promotion or marketing practices; and (iii) any probable violations of law. *See* CIA §§ III.I-K. Aegerion's failure to comply with the CIA could result in significant financial penalties and possible exclusion from federal health care programs. *See* CIA §§ X.A, D.

6. *The Consent Decree of Permanent Injunction*

The Company entered into a Civil Consent Decree of Permanent Injunction (the "Consent Decree") and will be closely monitored by the FDA for a period of at least five years. *See United States v. Gerrits, et al.*, Civil No. 17-cv-11818-MLW (D. Mass.) (Dkt. #4). Under the Consent

Decree, Aegerion must retain a qualified independent auditor to conduct annual audits of its compliance with the Juxtapid REMS program and remediate any noncompliance identified by the auditor. *Id.* at ¶ 11. In addition, Aegerion must certify compliance with the Consent Decree, post notice on its website regarding this comprehensive settlement, and provide a copy of the Consent Decree to an array of people. *See id.* at ¶¶ 16-19.

* * *

The settlement agreements impose a substantial financial penalty on Aegerion and significant ongoing government oversight. All of the settlement agreements contain severe financial penalties for non-compliance.

ARGUMENT

Criminal sentencing proceedings are guided by the factors set forth in 18 U.S.C. § 3553(a). The overarching principle of sentencing, known as the parsimony principle, is that the punishment imposed must be "sufficient, but not greater than necessary" to comply with the purposes of the statute. 18 U.S.C. § 3553(a). This principle "necessarily informs a sentencing court's consideration of the entire constellation of [S]ection 3553(a) factors," and a court should "strive to construct a sentence that is minimally sufficient to achieve the broad goals of sentencing." *United States v. Rodríguez*, 527 F.3d 221, 228 (1st Cir. 2008).

The sentence set forth in the Amended Plea Agreement is "sufficient, but not greater than necessary, to comply with the purposes set forth in" 18 U.S.C. § 3553(a)(2). *Id.* The terms provided in the Amended Plea Agreement provide adequate deterrence to future corporate misconduct, and reflect the seriousness of the offense committed by Aegerion. 18 U.S.C. § 3553(a)(2)(A)-(B).

I. THE PROPOSED SENTENCE SERVES THE PURPOSES OF SENTENCING SET FORTH IN 18 U.S.C. § 3553(A).

A. The Company Has Engaged In Extensive Cooperation with the Government Investigation and the Amended Plea Agreement Requires Continued Cooperation.

In May 2015 the independent directors of Aegerion assumed control of the Company's response to the Government Investigations. Since that time, Aegerion has provided extraordinary cooperation. [redacted]

[redacted]

B. Aegerion Has Undergone A Complete Transformation To Ensure That It Remains Compliant Going Forward.

As noted above, today's Aegerion is a fundamentally different company from the one described in the Information. Aegerion (i) operates under the supervision of a new board of directors, (ii) replaced its entire management team, and (iii) turned over a majority of its employees, including virtually its entire sales team. As the composition of Aegerion's management team and employees has changed, so too has the Company's culture of compliance, which has been materially improved both by Aegerion's revamped "tone from the top," as well as by its firm commitment to dedicate significant resources and energy to compliance.

1. *There Is Essentially No Overlap Between the Aegerion Board During the Relevant Timeframe Covered by the Information and the Novelion Board.*

Aegerion is subject to additional oversight by Novelion's Board of Directors, which consists of ten highly skilled individuals experienced in the pharmaceutical industry. The only member of the Board of Directors of Novelion who served on the Aegerion Board of Directors prior to January 2016 is Donald Stern, the former United States Attorney for the District of Massachusetts. Mr. Stern joined Aegerion's Board of Directors in the fall of 2015, following the board-directed internal investigation, which resulted in the resignations of Aegerion's former CEO and Chief Operating Officer ("COO"). Mr. Stern served as the first Chair of Aegerion's newly established Compliance Committee, and continues to serve as the chair of Novelion's Compliance Committee. Mr. Stern was specifically recruited by the board because it recognized the need to dramatically improve compliance oversight and leadership. In his role as Chair of the Compliance Committee, Mr. Stern draws on his deep DOJ experience and his tenure as Managing Director of

Corporate Monitoring & Consulting Services at Affiliated Monitors Inc., a consulting firm that provides independent integrity monitoring services and compliance services across a wide range of regulated industries.

Another critical step in transforming Aegerion's compliance culture was the hiring, in November 2015, of Roger Louis as Chief Compliance Officer. Mr. Louis, who is now Novelion's Chief Compliance Officer, has extensive experience in compliance and risk management, having served as Senior Vice President of Compliance & Risk Management and Chief Compliance Officer at Cubist Pharmaceuticals; Senior Vice President, Chief Compliance Officer at Biogen Idec; and Senior Vice President, Chief Compliance Officer at Genzyme. Mr. Louis is dedicated to establishing an effective and enduring compliance system.

2. *Aegerion's Former Senior Leadership Team has been Replaced by New Management.*

As noted above, Aegerion's management team has undergone a complete overhaul since the initiation of the Government Investigations. Marc Beer and Craig Fraser resigned as CEO and COO, respectively, in July 2015. Since the conduct described in the Information, Aegerion (and later Novelion) filled the following executive management roles with new leaders who are committed to compliance:

- Chief Executive Officer (January 2016);
- Chief Operating Officer (November 2017);
- General Counsel (September 2016);
- Head of Research and Development (November 2017);
- Senior Vice President of Regulatory (June 2017);
- Chief Compliance Officer (November 2015); and
- Chief Financial Officer (July 2015).

3. *The Majority of Aegerion's Current Employees Were Not Present at the Time of the Conduct Described in the Information.*

In the beginning of 2015, Aegerion employed 233 employees in the United States. Today, Aegerion employs 137 U.S. employees, most of whom work in Cambridge, and over half of those employees started with Aegerion after the events described in the Information. Moreover, only two sales representatives from Aegerion's pre-2017 U.S. sales force remain with the Company in any capacity. The remainder of the sales force departed voluntarily, were let go during a series of restructurings, or, in some cases, were terminated for cause, including as a result of thorough internal investigations into compliance issues. *See* 18 U.S.C. § 3572(a)(8) (instructing Courts to take note of measures by organizations to discipline employees).

4. *Despite its Financial Challenges, Aegerion has Dedicated Extensive Resources and Effort to Compliance and has Maintained a Focus on Patients.*

In the years since the period described in the Information, Aegerion has recommitted itself to a culture of compliance and a focus on patients. Despite the troubles it has faced, Aegerion has grown its compliance budget exponentially over the past few years. In 2016, while sales of Juxtapid declined by over 50% from 2015, Aegerion spent approximately $1.9 million on compliance. Over the past two years, Aegerion has hired a Global Chief Compliance Officer; a Vice President, Ethics and Compliance Officer; and a Senior Compliance Manager for U.S. Operations. These professionals oversee Aegerion's ongoing compliance efforts. To that end, one of the first actions undertaken by Mr. Louis was the engagement of Navigant Consulting ("Navigant") in 2016 to conduct an independent assessment of Aegerion's Compliance Program. Navigant has extensive experience in helping life sciences organizations build, refine, and assess compliance programs, and it frequently acts as an Independent Review Organization under corporate integrity agreements. Aegerion has used the results of Navigant's assessment to

enhance the effectiveness of its compliance program.

C. The Fine is Appropriate Because Aegerion's Ability To Pay Is Limited.

The fine set forth in the Amended Plea Agreement reflects Aegerion's ability to pay, and any greater fine or truncated payment period could jeopardize Aegerion's ability to recover and move forward. 18 U.S.C. § 3572(a) (instructing Courts to consider a defendant's financial resources when setting a fine); U.S.S.G. § 8C3.3 (noting ability of Court to reduce a fine in order to avoid jeopardizing the continued viability of an organization). As noted above, Aegerion's financial condition has been weakening. Since the agreement in principle was reached, sales of Juxtapid have continued to deteriorate and have fallen short of projections. [redacted]

In considering Aegerion's ability to pay, Aegerion respectfully requests that the Court also consider the patients who rely upon Juxtapid and Myalept. These two products treat severe, ultra-rare diseases. It is possible that an increased financial penalty could trigger a series of events that could seriously threaten the financial future of the Company, leaving its patients, who already live with a debilitating and dangerous condition, in a potentially dire situation. If this were to occur, patients who rely on Juxtapid or Myalept for treatment of their rare and severe disease will be left with few, if any, other options. *Cf*. 18 U.S.G. § 3572 (a)(2) (instructing courts to consider the burden on any person who is financially dependent on the defendant).

While PCSK9 inhibitors are prescribed to treat some HoFH patients, certain HoFH patients inadequately respond to such therapies due to certain types of genetic deficiencies.

Juxtapid is the only medication currently on the market that works by inhibiting microsomal triglyceride transfer proteins, which are responsible for transferring cholesterol from the liver. Thus, for some HoFH patients with genetic defects in their LDL receptor genes, Juxtapid may be the only medication on the market that sufficiently reduces their LDL-C levels.

Myalept is a leptin replacement therapy used to treat patients with the ultra-rare disease generalized lipodystrophy ("GL") and is the only therapy indicated to treat GL. GL is characterized by the widespread loss of fat tissue, typically from under the skin. Patients with GL often experience severe insulin resistance and diabetes, severe hypertriglyceridemia along with a concomitant increased risk of acute pancreatitis, and hepatic steatosis, which can lead to cirrhosis of the liver.

Finally, Aegerion currently provides approximately 231 patients—roughly 39% of patients on its therapies globally—with medicine at no cost. For these patients, Juxtapid and Myalept provide essentially the sole treatment option for a serious illness for which there is no identical alternative treatment.

II. THIS CASE IS ONE OF THE "RARE CIRCUMSTANCES" THAT MERITS A (C) PLEA.

The sentence presented to this Court for approval is a fair and appropriate sanction for Aegerion's past conduct. Moreover, given the circumstances before the Court, this case presents the rare circumstance that warrants acceptance of a plea submitted under Rule 11(c)(1)(C). *See United States v. Orthofix, Inc.*, 956 F. Supp. 2d 316, 320 (D. Mass. 2013).

A. Aegerion's Amended Plea Agreement Does Not Suffer From The Defects Of The Orthofix And APTx Pleas.

The Amended Plea Agreement fills in where the Orthofix plea fell short. *See id.* at 332–33 (identifying failure to impose term of probation and include non-disparagement provision as primary areas of concern). Unlike in *Orthofix*, Aegerion's Amended Plea Agreement includes a

term of probation. Am. Plea Agmt. ¶ 5(e). The Court has discretion to set probation between three and five years, with a term of five years being the maximum term of probation suggested by the Sentencing Guidelines for an Organizational Defendant. *See* U.S.S.G. § 8D1.2. The Amended Plea Agreement also allows the Court discretion to impose the standard terms of probation that the Court finds appropriate. Am. Plea Agmt. ¶ 5(e).

The Amended Plea Agreement also includes several special terms of probation. Most notably, as a special condition of probation, Aegerion and its current employees and agents may not "disparage the factual basis of Aegerion's guilty pleas or deny acceptance that the corporation itself is guilty of the offenses of conviction." *Id.* ¶ 5(e)(i). The Amended Plea Agreement also includes Aegerion's continued compliance with the DPA and the CIA as conditions of probation, which provides the Court with authority to respond to violations of Aegerion's compliance obligations. *Id.* ¶¶ 5(e)(iv-v). These provisions will allow the Court to protect "the public interest and [preserve] the normative character of the criminal law." *Orthofix,* 956 F. Supp. 2d at 334. As this Court has observed, a term of probation "ensure[s] that changes are made within the organization to reduce the likelihood of future criminal conduct." *Id.* at 333 (quoting U.S.S.G. § 8D1.1(a)(6)).[1]

The Amended Plea Agreement also accommodates the Court's policy concerns regarding "specific and general deterrence," "respect for the law," and, most importantly, "the protection of the public." *See id.* at 327. With regard to deterrence, the Amended Plea Agreement imposes financial and punitive measures that discourage Aegerion, or any other corporate entity, from

[1] The Amended Plea Agreement also avoids the shortcomings of the APTx plea agreement by imposing a $7.2 million criminal fine and forfeiture, in addition to approximately $33 million in civil penalties. Given Aegerion's precarious financial situation, the criminal and civil fines and penalties are a far cry from the "bargain-basement," "strikingly low" fines that doomed the APTx plea. *See Orthofix*, 956 F. Supp. 2d at 335.

breaking the law. Unlike Orthofix, which had substantial assets and profits at the time of sentencing, Aegerion's financial penalties are the maximum Aegerion can afford without "substantially jeopardizing the continued viability of the organization." U.S.S.G. § 8C3.3(b)). The financial penalties contained in the Amended Plea Agreement and the related settlement agreements combine to push Aegerion to the limit financially, and serve as a potent deterrent to other companies.

Other settlement provisions enhance the deterrent effect, such as requiring Aegerion to admit its misconduct publicly. In addition to admitting the facts alleged in the Information, the DPA, CIA, and Consent Decree require Aegerion to publish a notice on the Company's website and send widespread notifications informing the public that it is pleading guilty to criminal misconduct, affecting its reputation. These penalties—on top of mandatory government oversight—will discourage other companies from violating the law. Coupled with the non-disparagement provision, these mandatory disclosures ensure that the public is not "deprived of ever knowing the truth in a matter of obvious public importance." *Orthofix*, 956 F. Supp. 2d at 326; *see id.* at 333–34. Finally, the plea affords efficiency and practicality, two "important component[s] of justice," *id.* at 337, by providing Aegerion—and, going forward, other corporations—the narrow opportunity to avail themselves of a Rule 11(c)(1)(C) plea in appropriate circumstances, as are present in this case.

B. Circumstances Have Changed Since The Orthofix And APTx Pleas, Especially With Regard To DOJ's Charging Determinations As To Corporate Defendants.

On September 9, 2015, DOJ issued the "Yates Memo" to federal prosecutors emphasizing the importance of prosecuting the individuals responsible for the underlying wrongdoing when combatting corporate crime. Corporate cooperation is an important tool for prosecutors to identify and gain access to relevant witnesses and documents that are crucial to prosecuting individual

wrongdoers. Rule 11(c)(1)(C) pleas provide a strong incentive for corporate criminals to cooperate to the fullest extent possible, because prosecutors can offer some sense of certainty when negotiating a resolution to a criminal case. Entering into a (C) plea offers a corporation certainty as to sentencing, including potential fines and probation, which can mitigate collateral consequences on employees, shareholders, investors, and other interested parties. The existence of (C) pleas in the corporate context, thus, serves the goals of the Yates Memo and the DOJ, more broadly, in creating an optimal environment in which to hold individuals accountable for their crimes.

C. Refusing To Consider A (C) Plea For A Corporate Defendant Would Result In Disparate Sentences for Criminal Defendants in this District Compared to Other Districts.

Entering into a Rule 11(c)(1)(C) plea is often a corporation's only plea option to resolve criminal charges, as the uncertainty in sentencing inherent in Rule 11(c)(1)(B) pleas causes too great a risk to innocent employees, shareholders, investors, and other interested parties. Of course, the Court should not accept a (C) plea without first determining whether the plea is fair, appropriate, and in the best interest of the public. Moreover, there is no absolute right to have a guilty plea accepted. However, if (C) pleas are unavailable or severely limited, corporations negotiating with the government in cases in the District of Massachusetts will operate under a different set of rules than defendants prosecuted in other districts. *Cf. United States v. Reyes-Santiago*, 804 F.3d 453, 467 (1st Cir. 2015) ("In fashioning an appropriate sentence, judges are directed by statute to consider 'the need to avoid unwarranted sentencing disparities among defendants with similar records who have been found guilty of similar conduct.'").

Notably, the vast majority of corporate criminal charges involve (C) pleas.[2] Since Orthofix

[2] In recent years, a number of pharmaceutical companies have plead guilty to criminal conduct pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the District of Massachusetts. *See, e.g.*, Plea

pled guilty in December 2012, at least 85 companies have had (C) pleas accepted by federal courts. For example, in October 2015, Warner Chilcott pled guilty pursuant to Rule 11(c)(1)(C) to a felony charge of health care fraud relating to the company's illegal marketing of several drugs in the District of Massachusetts. *See* Plea Agreement, *United States v. Warner Chilcott Sales (U.S.) LLC*, No. 15-cr-10327-DFS (D. Mass. 2016) (Dkt. #2). Similarly, in November 2016, Biocompatibles Inc. pled guilty pursuant to Rule 11(c)(1)(C) to a misbranding violation under the Food, Drug, and Cosmetic Act in the District Court for the District of Columbia. *See* Plea Agreement at 3, *United States v. Biocompatibles, Inc*., No. 1:16-mj-00710 (D.D.C. Nov. 7, 2016) (Dkt. #9). OtisMed Corp. also pled guilty to criminal conduct pursuant to Rule 11(c)(1)(C) in the District of New Jersey. *See* Plea Agreement at 3, *United States v. OtisMed Corp.*, No. 2:14-cr-00688-CCC (D.N.J. Dec. 8, 2014) (Dkt. #3). Rule 11(c)(1)(C) pleas are also used widely in other industries outside of the pharmaceutical and medical device industries. For example, just over a month ago, Tyson Poultry pled guilty to a Clean Water Act charge through a (C) plea in the Western District of

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Agreement at 2, *United States v. Warner Chilcott Sales U.S. (LLC)*, No. 15-cr-10327 (D. Mass. Oct. 29, 2015) (Dkt. #2); Plea Agreement at 3, *United States v. GlaxoSmithKline LLC*, No. 12-cr-10206 (D. Mass. July 2, 2012) (Dkt. #2); Plea Agreement at 6, *United States v. Merck Sharp & Dohme Corp.*, No. 11-cr-10384 (D. Mass. Dec. 12, 2011) (Dkt. #12); Plea Agreement at 3, *United States v. Elan Pharm., Inc.*, No.10-cr-10431 (D. Mass. Feb. 28, 2011); Revised Plea Agreement at 8, *United States v. SB Pharmco Puerto Rico, Inc.*, No. 10-cr-10355 (D. Mass. Nov. 8, 2010) (Dkt. # 10); Plea Agreement at 10, *United States v. Forest Pharm., Inc.*, No. 10-cr-10294 (D. Mass. Sept. 15, 2010) (Dkt. #7); Plea Agreement at 5, *United States v. Ortho-McNeil Pharm., LLC*, No. 10-cr-10147 (D. Mass. Apr. 29, 2010) (Dkt. #3); Plea Agreement at 3, *United States v. Pharmacia & Upjohn Co.*, No. 09-cr-10258 (D. Mass. Sept. 2, 2009) (Dkt. #2); Plea Agreement at 3, *United States v. Biovail Pharm., Inc.*, No. 08-cr-10124 (D. Mass. Sept. 14, 2009); Plea Agreement at 1, *United States v. Bryan Corp.*, No. 07-cr-10353, (D. Mass. Dec. 20, 2007.) (Dkt. #5); Plea Agreement at 3, *United States v. Pharmacia & Upjohn Co., Inc.*, No. 07-cr-10099 (D. Mass. Apr. 3, 2007) (Dkt. #2); Plea Agreement at 3, *United States v. Schering Sales Corp.*, No. 06-cr-10250-RBS (D. Mass. Sept. 20, 2006) (Dkt. #12); Plea Agreement at 5, *United States v. Serono Laboratories, Inc.*, No. 05-cr-10282 (D. Mass. Dec. 21, 2005) (Dkt. #7); Plea Agreement at 2, *United States v. Warner-Lambert Co. LLC*, No. 04-cr-10150-RGS (D. Mass. May 13, 2004) (Dkt. #2); *United States v. Bayer Corp.*, No. 03-cr-10118-RG (D. Mass. May 8, 2003) (Dkt. #7); Plea Agreement at 2, *United States v. TAP Pharm. Products, Inc.*, No. 98-cv-10547 (D. Mass. Oct. 1, 2001) (Dkt. #44).

Missouri. *See* Plea Agreement at 1, *United States v. Tyson Poultry, Inc.*, No. 3:17-cr-05041 (W.D. Mo. Sept. 27, 2017) (Dkt. #8).

Aegerion does not reference these other pleas to suggest that this Court should accept corporate (C) pleas in all circumstances. The Company understands that this Court must thoroughly assess the public interest and the judiciary's unique role in sentencing when determining whether a corporate (C) plea is appropriate. Some corporate (C) plea agreements achieve the high bar this Court articulated in the Orthofix and APTx cases. Aegerion respectfully submits that this (C) plea meets this standard.

REQUEST FOR ORAL ARGUMENT

Aegerion respectfully requests that the Court accept its Rule 11(c)(1)(C) guilty plea and impose a sentence within the parameters of the Amended Plea Agreement. The importance of the Court's decision on this plea, and the magnitude of potential harm to the future of the Company and its employees, investors, and stakeholders, cannot be overstated. The ability of the Company to survive depends on the outcome of this proceeding. This case meets the "rare circumstances" where a (C) plea should be accepted. Given these circumstances, Aegerion respectfully requests an opportunity to be heard on the merits of the Amended Plea Agreement.

Dated: November 1, 2017

Respectfully submitted,

Boston, Massachusetts

/s/ Joshua S. Levy

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

Dated: November 1, 2017

/s/ *Patrick J. Welsh*
Patrick J. Welsh